

JUL 13 2001

KO11257

Ethicon Endo-Surgery, Inc.

510(k) Premarket Notification for ENDOPATH® Non-Bladed Obturator Trocar System

ENDOPATH® Non-Bladed Obturator Trocar System (5 mm) 510(k) Summary of Safety and Effectiveness

Company

Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact

Katie Fordyce
Regulatory Affairs Associate

Date Prepared:

April 23, 2001

Name of Device

Trade Name: ENDOPATH® Non-Bladed Obturator Trocar System (5 mm)
Classification Name: Laparoscope, General & Plastic Surgery

Predicate Devices: ENDOPATH Non-Bladed Obturator Trocar System

Device Description: The ENDOPATH Non-Bladed Obturator consists of an obturator and a sleeve. The clear, tapered optical element, when used with an endoscope, provides visibility of individual tissue layers during insertion. The blunt tip may reduce risk of trauma to abdominal viscera. An insufflation adapter, when supplied, is compatible with standard luer lock fittings and provides for insufflation of the abdominal cavity. The ENDOPATH Non-Bladed Obturator has a sealing range that accommodates appropriately sized instruments. The obturator accommodates an appropriately sized zero degree endoscope.

Intended Use: The ENDOPATH Non-Bladed Obturator has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

Technological Characteristics: The technological characteristics of the new device are the same as those of the predicate device with the exception of the optical tip. The tip material and method of attachment of the tip to the shaft are the two characteristics that differ from the predicate device to the new device.

Performance Data: Preclinical testing was performed to ensure that the device performs as intended when used according to the instructions for use. Animal testing demonstrated that the new device performed satisfactorily when compared to the predicate device. The specifications for the bench testing were all met.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2001

Ms. Katie Fordyce
Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K011257

Trade/Device Name: ENDOPATH® Non-Bladed Obturator Trocar System
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: April 23, 2001
Received: April 24, 2001

Dear Ms. Fordyce:

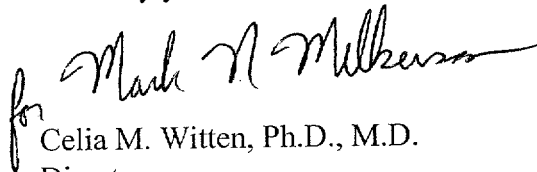
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Mark N. Milken

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K011257

Device Name: ENDOPATH® Non-Bladed Obturator Trocar System

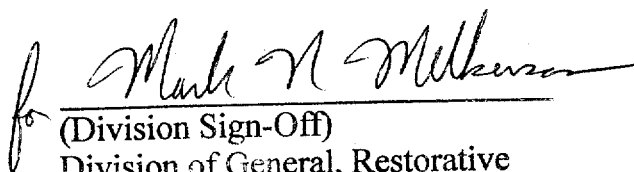
Indications for Use:

The ENDOPATH Non-Bladed Obturator has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)


(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K011257